

Terms and Conditions of Service for Referrers

LabPLUS Terms and Conditions of Service HER2 in Breast Tissue by Fluorescent in situ Hybridisation Testing

LabPLUS is the exclusive provider of a National Service for the analysis of HER2 in breast tissue by Fluorescent in situ Hybridisation (“FISH Testing”) funded by Roche Products (New Zealand) Limited (“Roche”). The FISH Testing services (“the Services”) are offered to all referring laboratories, pathologists, oncologists and breast surgeons (“the Referrers”) by LabPLUS on and subject to these Terms and Conditions of Service (“Terms”).

A Referrer shall be deemed to have accepted these Terms when providing a specimen and requesting a FISH Test.

1. Eligibility for FISH Testing

- 1.1 The Referrer acknowledges that the following criteria have been established for undertaking the FISH Testing and only a specimen of breast tissue meeting these criteria (“Valid Specimen”) will be analysed by LabPLUS at no charge to the Referrers:
- (a) the Referrer must have collected and submitted the specimen to LabPLUS in a manner that complies with the Referrer’s obligations as set out in these Terms; and
 - (b) the specimen submitted by the Referrer must have been analysed by Immunohistochemistry (IHC), and using the commonly used HercepTest scoring system :
 - (i) has been scored as 2+ ; or
 - (ii) has been scored as 1+ or 3+ and, based on a reasonable justification provided by the Referrer, the LabPLUS cytogeneticist has exercised his or her discretion to perform the analysis, which may be performed for a maximum of 2 tests each month (across all Referrers) unless the Client has otherwise given its prior written consent to the test.
- 1.2 Specimens that meet the above criteria will be analysed by LabPLUS at no charge to the Referrer. Subject to the terms of the Services Agreement between LabPLUS and Roche, Roche has agreed to pay LabPLUS for the costs of these qualifying FISH Tests.
- 1.3 If a specimen falls outside the above criteria or Roche is not required to pay for the FISH Test under the Services Agreement between LabPLUS and Roche, then LabPLUS will advise the Referrer and will only undertake the FISH Test if expressly requested by the Referrer and with the Referrer’s agreement that the Referrer will be liable for the cost of the FISH Test at LabPLUS’s then applicable standard rate for a FISH Test.
- 1.4 LabPLUS reserves the right to refuse to provide the Services to a Referrer if Roche has withdrawn or limited its support for these Services or the Referrer has not complied with the Referrer’s obligations under these Terms.

2 **Obligations of the Referrer**

2.1 **Specimen Collection:**

- (a) The Referrer will provide specimen receptacles appropriate for the FISH Test specimens.
- (b) The Referrer will collect specimens and provide them in a form detailed in the LabPLUS Handbook for FISH Testing by LabPLUS. Refer also the "Special Instructions for HER2 Fish Testing analysis".

2.2 **Patient Registration:**

- (a) The Referrer's staff will register demographics including a unique identifier into its laboratory computer database.
- (b) The Referrer will assign laboratory accession numbers establishing a traceable audit trail for the patient, specimen and the requested Fish Tests.

2.3 **Specimen Handling:**

The Referrer will:

- (a) ensure adequate labelling of specimens;
- (b) process the samples as appropriate for the requested tests;
- (c) package specimens and request forms into courier packs supplied by LabPLUS;
- (d) detail a packing slip with each consignment to include listing of patient's name, laboratory accession number and test(s) requested;
- (e) facilitate compliance with LTSA regulations and prepare consignments of specimens for courier collection at the agreed times;
- (f) clearly indicate the destination(s) for report delivery; and
- (g) document the identity of the requesting doctor unambiguously.

2.4 **Results Reporting and Archiving:**

- (a) The Referrer will maintain an overdue list of reports in excess of the standard turn around time for each test as indicated in the LabPLUS Handbook.
- (b) The Referrer dispatch staff will receive results from LabPLUS.
- (c) The Referrer will copy results and interpretive comments into their computer database, annotating the result with acknowledgement of the reference laboratory, which performed the analyses.
- (d) The Referrer will store results in accordance with the Referrer's laboratory policy and quality management protocols.

2.5 **The Referrer's Warranties:**

The Referrer warrants to LabPLUS and Roche that the Referrer:

- (a) has obtained all necessary rights, permits, licences or authorisations to provide the specimens to LabPLUS for testing; and
- (b) will carry out its obligations under these Terms in compliance, in all respects, with these Terms and with the laws and regulations in force in New Zealand.

3 **OBLIGATIONS UNDERTAKEN BY LABPLUS**

3.1 **Acknowledgement of Receipt of Specimens:**

- (a) LabPLUS will ensure that the Referrer has correctly completed the FISH Test request form before analysis of the specimen begins.
- (b) The details of any specimens that are unsatisfactory on receipt will be communicated by LabPLUS to the Referrer as soon as possible.

3.2 **Analysis and Documentation:**

- (a) LabPLUS will carry out analyses of each Valid Specimen as detailed on the Referrer's FISH Test request form.
- (b) LabPLUS will implement a traceable audit trail for the processing of all referred specimens.
- (c) LabPLUS will provide result reports to the Referrer. The results will include reference ranges and interpretive comment for significantly abnormal results where appropriate.
- (d) Turnaround times for the FISH Testing is detailed in the LabPLUS Electronic Handbook detailed on the LabPLUS website www.labplus.co.nz. LabPLUS will provide the results to the Referrer within 5-10 Business Days from the day of receipt of the specimen and the Referrer's request.
- (e) LabPLUS will report delays to the Referrer if agreed turnaround times (5-10 Business Days) are to be exceeded.

3.3 **Reporting to Referrers:**

- (a) LabPLUS will report changes in reference ranges or methodologies before results are transmitted to the Referrer.
- (b) LabPLUS will provide written reports of the results of the FISH Testing for each Valid Specimen by post or by facsimile and where the capability is established, reports may be transmitted electronically using HL-7 formatted data directly from LabPLUS to the computer database of the Referrer ("Electronic Transmission"). LabPLUS will ensure that each Electronic Transmission is correctly formatted and validated in conformance with current HL-7 standards.

- (c) LabPLUS will ensure that each report to a Referrer contains:
 - (i) that Referrer's accession number(s);
 - (ii) reference ranges; and
 - (iii) interpretive comment for significantly abnormal results where appropriate.
- (d) From time to time, oral reports of urgent or significantly abnormal results may be telephoned directly to the staff of the Referrer. LabPLUS must confirm these reports to the Referrer in hardcopy or electronic form.

3.4 **Reporting to Roche:**

- (a) LabPLUS will report every second month to Roche the following demographic data:
 - (i) Age of referred patient.
 - (ii) Diagnosis, tumour type +EBC or MBC.
 - (iii) IHC status.
 - (iv) Hormonal status.
 - (v) Referring Doctor.
 - (vi) FISH result.
 - (vii) Turnaround Times.
- (b) LabPLUS will supply all relevant information relating to methodology, quality assurance performance and clinical interpretation in respect of the Services on request by Roche.

3.5 **Customer Services Access:**

- (a) LabPLUS will maintain a Website with up-dated information, LabPLUS's Electronic Handbook and other communication tools.
- (b) LabPLUS will maintain a free phone 0800 LABPLUS (0800 5227587) for direct access for information relating to the referred Fish Tests.
- (c) LabPLUS staff directly involved that may be contacted are:
 - (i) Alice George, Technical Head. Tel 09 307 4949 ext 6396;
 - (ii) Dr Jane Evans, Consultant Anatomical Pathologist. Tel 09 307 4949 ext 2061.
- (d) Other LabPLUS staff that may be contacted:
 - (i) Cheryle Dyson, Business Development Manager Tel 09 307 8995, Mob 021 156 5178
 - (ii) Ross Hewett, LabPLUS Laboratory Manager. Tel 09 307 8995 Mob 021 439 388.

- (e) LabPLUS will provide any Referrer with reasonable access to LabPLUS' Specialist Pathologists and Registered Medical Laboratory Scientists to respond to enquiries and assist with interpretation of the Referrer's FISH Test results.

3.6 **Compliance:**

LabPLUS warrants that it:

- (a) has obtained all necessary rights, permits, licences or authorisations to provide the Services;
- (b) will carry out its obligations under these Terms with reasonable care, skill and diligence and will employ techniques of a high quality and standard and in accordance with best industry practices;
- (c) will maintain registration with International Accreditation New Zealand (IANZ) for ISO 15189;
- (d) will ensure those scientists involved in the preparation, analysis and reporting of the FISH Her2 tests are Registered Medical Laboratory Scientists or Technicians and hold Annual Practising Certificates with the Medical Laboratory Science Board of New Zealand;
- (e) will remain an accredited laboratory with the College of American Pathologists for HER2 testing for the duration of this Agreement; and
- (f) will carry out its obligations under these Terms in compliance, in all respects, with the laws and regulations in force in New Zealand.